

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

<b>IN RE: VALSARTAN N-</b>	<b>:</b>	<b>HON. ROBERT B. KUGLER</b>
<b>NITROSODIMETHYLAMINE (NDMA)</b>	<b>:</b>	
<b>CONTAMINATION PRODUCTS</b>	<b>:</b>	<b>MASTER DOCKET NUMBER</b>
<b>LIABILITY LITIGATION</b>	<b>:</b>	<b>Civil No. 1:19-md-02875-RBK-JS</b>
	<b>:</b>	
<b>This Document Relates to All Actions</b>	<b>:</b>	

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**DECLARATION OF MATTHEW SAMPLE**

I, Matthew Sample, hereby declare as follows:

1. I am Vice President of Manufacturing Operations for AmerisourceBergen Corporation (“ABC”), and as part of my job duties and responsibilities, I am familiar with ABC’s practices regarding the Drug Supply Chain Security Act (“DSCSA”) and its implementation at ABC.

2. The DSCSA, enacted in 2013, sets forth the product tracing requirements for each level of the pharmaceutical supply chain. The DSCSA does not require ABC to include the lot number in the documents and data ABC has provided to a purchaser of a Valsartan-containing products (“VCD”) because the DSCSA expressly exempts ABC from lot-level product tracing requirements.

3. The lot number of a VCD is included in the documents ABC receives with each shipment of a VCD from a Manufacturer. The document containing this information is a “T3 document.” The DSCSA provisions providing for the T3 document took effect in 2015.

4. ABC does not input the lot number on the T3 document into their own data systems and ABC does not pass the lot number on as part of a sale. ABC has no records or data that could connect a specific lot number of a VCD purchased from a Manufacturer to the sale of a VCD to a Retailer. Also, ABC is not required to and does not track expiry dates of the VCDs it sells.

5. In order to trace the lot number of a VCD ABC received from a Manufacturer between January 1, 2012 and December 31, 2019 (“the time period”), and then link that lot number to a sale of a VCD to a particular Retailer, ABC would have been required to manually inspect and manually enter that information into their sales systems for each VCD sold. ABC’s yearly transactions during the time period numbered in the several hundreds of millions.

6. The work that would have been required to manually inspect and manually enter lot numbers of VCDs received from Manufacturers during the time period into ABC’s sales system would have increased ABC’s operations expense significantly, burdened the supply chain, slowed down shipments, impacted the delivery of pharmaceuticals to patients in need, and significantly impacted ABC’s profits with respect to the sale of VCDs. There was no commercial reason for ABC to incur those costs, delays and burdens.

7. Pursuant to the DSCSA, by November 27, 2023, all wholesalers must have an electronic, interoperable system in place to trace products at the package level.

8. During the time period, ABC entered into Supplier Agreements with Manufacturers (“Supplier Agreements”), pursuant to which Manufacturers agreed to provide a variety of pharmaceuticals, listed by National Drug Code (NDC) numbers, to ABC pursuant to various price calculations.

9. Those Supplier Agreements did not relate to one specific drug or class of drugs, but instead covered a variety of drugs and classes of drugs. Each pharmaceutical product ABC received from a manufacturer/labeler was received in a container or other package bearing an NDC number, which is comprised of a labeler code, a product code and container size code. The labeler code is assigned by FDA to each entity that labels drug products. The product code and container size code are assigned by the labeler. Differences in strength and route of administration result in

different product codes for the same drug substance from the same labeler, contributing to the vast number of NDC numbers on pharmaceutical products purchased and sold by ABC.

10. Pursuant to the Supplier Agreements, during the time period ABC purchased pharmaceuticals, including VCDs, from Manufacturers on an as-needed basis.

11. During the time period, ABC also entered into agreements with Retailers (“Retailer Supplier Agreements”), pursuant to which ABC agreed to provide a variety of pharmaceuticals, listed by NDC numbers, to Retailers pursuant to various price calculations.

12. Pursuant to the Retailer Supplier Agreements, Retailers made individual purchases of pharmaceuticals from ABC on an as-needed basis.

13. When ABC delivered the pharmaceuticals sold to the Retailers, ABC transferred certain T3 information to Retailers. However, ABC’s sales systems did not have any lot number information and ABC did not link the lot numbers obtained from purchases from Manufacturers to product sold to Retailers.

14. The lot number of a VCD sold by ABC cannot be included in any sales history report ABC could generate because ABC is not required to and does not maintain that information, as described in paragraphs 2, 3 and 4 above.

15. The searches required to generate any sales history report for all VCDs sold by ABC from January 1, 2012 to December 31, 2019, would require a significant investment of time and expense by ABC and would be extremely burdensome on both ABC’s employees and IT resources, especially at this time given the ongoing COVID 19 crisis and ABC’s role in responding to the crisis.

16. ABC does not, in the ordinary course of business, calculate profits from particular NDC numbers or by pharmaceutical products. ABC has not, in the ordinary course of its business from 2012 to the present, calculated profits from sales of VCDs.

17. If it could be done, calculating such profits would require a significant expenditure of time and resources by ABC. ABC would be required to determine all of the expenses, taxes and overhead attributable to VCDs only over eight years. To determine expenses, taxes and overhead attributable to eight years-worth of VCD sales would require significant additional data collection and work, resulting in diversion of ABC employees from normal business operations, and the use of accounting and financial experts to make sure profits were accurately stated.

18. There are significant competitive and commercial sensitivities and issues associated with generic pharmaceutical product pricing, and ABC closely protects its confidential and proprietary data and information about sourcing, pricing and distributing pharmaceutical products. ABC does not disclose non-public pricing information outside of the company.

19. The pricing and selling of generic pharmaceutical products is more complicated than that of name-brand drugs. With a name-brand drug, there is typically only one manufacturer. In contrast, FDA may approve multiple (sometimes a dozen or more) entities to manufacture and sell a particular generic pharmaceutical product, resulting in different commercial terms with different manufacturers for the same generic pharmaceutical product. Also, there are generic products that are in multiple formulations or routes of administration, further adding to the complexity surrounding the sourcing and pricing of generic pharmaceutical products.

20. ABC sources generic drugs from multiple entities with varying contracts, containing many different pricing structures. ABC considers their non-public information

regarding sourcing and pricing of generic drugs to be commercially highly sensitive, highly confidential, and trade secrets.

21. The business environment regarding generic drug sales is highly competitive among and across the various entities sourcing pharmaceutical products and selling generic pharmaceutical products to retail pharmacy chains.

22. Retail pharmacies compete with each other to source generic pharmaceutical products and they negotiate the most competitive pricing for generic pharmaceutical products with wholesalers. The viability of ABC's generic drug business requires that the confidentiality of pricing information be carefully maintained, given the risk of loss of significant competitive and economic advantage and/or the possible loss of customers in litigation involving manufacturer/suppliers, customers, and competitors.

23. Nearly every defendant in this litigation is a manufacturer/supplier, a customer, or a competitor of ABC in some fashion. ABC takes great care to ensure that manufacturers/suppliers, competitors, and/or customers do not obtain access to or learn of ABC's confidential financial data, pricing information, and/or commercial information. Disclosure of such sensitive and confidential pricing information and other commercial and financial information to the public and/or to other defendants who are parties to this litigation imposes upon ABC the risk of altering the current competitive balance for ABC in the generic pharmaceutical product market. It could also adversely impact ABC's ability to negotiate future sales and sourcing contracts.

I declare under penalty of perjury that the foregoing is true and correct, and that this Declaration was executed June 16, 2020.

Matt Sample, VP Mfg Operations

A handwritten signature in black ink, appearing to be 'MS' followed by a long horizontal stroke.